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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/648,464

08/25/2003

James D. Ralph

F-286

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09/10/2008

SPINE MP

LERNER, DAVID, et al.

600 SOUTH AVENUE WEST

WESTFIELD, NJ 07090

EXAMINER

BLANCO, JAVIER G

ART UNIT

PAPER NUMBER

3774

MAIL DATE

DELIVERY MODE

09/10/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

Response to Amendment

1. Applicants' amendment of claims 13, 16, 21, 29, 32, and 35 in the reply filed on June 16, 2008 is acknowledged.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 29, 32, and 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Regarding each of claims 29, 32, and 35, the limitation "the first end" lacks antecedent basis.

b. Regarding each of claims 29, 32, and 35, the limitation "wherein said spring has holes a first hole at the first end thereof and a second hole at a second end thereof" is unclear, and indefinite as to the scope of the invention. It is unclear how a "first end" and a "second end" relate to the claimed "spring" or "socket" since none of independent claims 13, 16, and 21 provides structure for the "spring" or "socket". Critical structure necessary for accomplishing the claimed function must be set forth. This limitation will be broadly interpreted.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 13, 16, 18, 20, 21, 23, 27, 28, 30, 31, 33, and 34 are rejected under 35

U.S.C. 102(b) as being clearly anticipated by **Berry** (US 5,895,428; cited in Applicants' IDS).

As seen in Figures 9 and 11, Berry discloses an intervertebral spacer device comprising a first plate (plate 35 of fitting 101) and a second plate (**first interpretation:** fitting 103; **second interpretation:** fitting 105; **third interpretation:** fitting 103 + fitting 105), each having an exterior surface thereof and inner surfaces facing one another, wherein an inner surface of said first plate (35) comprises a ball-shaped structure (spherical nut 13, which is part of member 35 via attachment to screw 47) extending therefrom and an inner surface of the second plate has a spring/socket (**first interpretation:** fitting 109; **second interpretation:** fitting 109 + fitting 105) affixed thereto at one or more locations (e.g., threads 111, 123) such that at said one or more locations there is no movement of said spring relative to said second plate in any direction (e.g., once assembled, the spring/socket is locked/fixed to the fitting or plate), said spring having an opening/curvate volume (see Figures 9 and 11). Said spring/socket has a top side with a curved convex surface (e.g., curved convex surface of fitting 109) that extends from the curvate volume and confronts said inner surface of said first plate (35), and an underside with a curved concave surface (**first interpretation:** curved concave surface of fitting 109; **second interpretation:** curved concave bottom surface of fitting 105) that extends from the curvate volume and is spaced from and confronts said inner surface of said second plate. Berry disclose the implant as

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made from either metal and/or ceramic (see column 6), and the spring as able to counteract the load applied to at least one of the plate.

With regards to statements of intended use and other functional statements (e.g., adapted to; etc.), they do not impose any structural limitations on the claims distinguishable over the device of **Berry**, which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959). “[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

6. Claims 13, 16, 18, 20, 21, 23, 27, 29, 30, 32, 33, and 35 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by **Xavier et al.** (US 6,063,121 A).

As seen in Figures 1-5, Xavier et al. disclose an intervertebral spacer device (10) comprising first (20) and second (48) plate members, each having an exterior surface thereof and inner surfaces facing one another, wherein an inner surface of one of said plate members comprises a ball-shaped structure (ball supporting member 42 + ball 46, or ball 46 by itself) extending therefrom and an inner surface of the other one of said plate members has a spring (**first interpretation:** socket-supporting member 62 and socket 68; **second interpretation:** cushion 80 by itself; **third interpretation:** socket-supporting member 62 + socket 68 + cushion

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80, as an assembly; **fourth interpretation:** socket 68 by itself) affixed thereto at one or more locations (**first interpretation:** socket-supporting member 62 is part of, therefore affixed to, second plate 48; **second interpretation:** surface 86 of cushion 80 is locked/fixed to second plate 48) such that at said one or more locations there is no movement of said spring relative to said second plate in any direction (e.g., once assembled, the spring/socket is locked/fixed to the second plate), said spring having an opening/curvate volume (**first interpretation:** socket 68; **second interpretation:** central aperture 90 of cushion 80; **third interpretation:** socket 68 + central aperture 90 of cushion 80). Xavier et al. disclose socket supporting member 62, socket 68, ball supporting member 42, and ball 46 as made from either metal or ceramic (see column 4, lines 50-64), and able to counteract the load applied to at least one of the plate members (see column 4, lines 11-20). The spring/socket having a top side with a curved convex surface (**first interpretation:** as seen in Figure 3, the top circumferential edge or surface of socket 68 is curved AND convex; **second interpretation:** as seen in Figure 3, the top circumferential edge of cushion 80 is curved AND convex) that extends from the curvate volume and confronts the inner surface of the first plate, and an underside with a curved concave surface (e.g., surface 70 of socket 68 is curved and concave) that extends from the curvate volume and is spaced from and confronts (e.g., face) the inner surface of the second plate.

Regarding claims 29, 32, and 35, said claims has 112 2nd paragraphs issues. Plates or extensions 34 comprises through holes with fasteners 38 extending through said holes that further contributes to secure the spring/socket to the second plate. These structures are capable of securing the spring to the second plate (e.g., when the prosthesis is finally assembled).

With regards to statements of intended use and other functional statements (e.g., adapted to; for securing; etc.), they do not impose any structural limitations on the claims distinguishable over the device of **Xavier et al.**, which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959). “[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 14, 15, and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Xavier et al.** (US 6,063,121 A) in view of **Stubstad et al.** (US 3,867,728 A; cited in Applicants’ IDS).

Xavier et al. disclose the invention as claimed (see 102(b) rejection above). Xavier et al. did not particularly disclose said external plate surfaces as having a deflectable/deformable surface (or mesh) thereon. However, this is well known in the art. For example, Stubstad et al.

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disclose (see Figures 1, 2, and 4) an intervertebral spacer device (device 10) comprising: (i) first (top element 11) and second (bottom element 12) plate members, each having an external plate surface, at least one of the external plate surfaces having a deflectable/movable (i.e., capable of being deflected/moved; see column 8, lines 46-49; column 9, lines 14-17), convex (see Figure 4; see column 13, lines 24-26), wire mesh (e.g., Dacron mesh 21 and/or Dacron mesh 20; see column 8, lines 6-10 and lines 43-59; column 9, lines 10-18). The device further comprises a force-restoring element (e.g. core 15) disposed between the first and second plate members (see entire document). Stubstad et al. teach said deflectable/deformable, convex wire mesh disposed on said external plate surfaces in order for the external plate surfaces to adapt/match to any small irregularities in the vertebral surfaces and to enable deeper tissue ingrowth on said external plate surfaces (see columns 8 and 9). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of an intervertebral spacer device comprising external plate surfaces having a deflectable/deformable, convex wire mesh thereon, as taught by Stubstad et al., with the intervertebral spacer device of Xavier et al., in order for the external plate surfaces to adapt/match to any small irregularities in the vertebral surfaces and to enable deeper tissue ingrowth on said external plate surfaces.

As noted by the United States Supreme Court, if a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill. *KSR*, 127 S. Ct. at 1740. "When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable

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solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product is not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show it was obvious under 35 U.S.C. 103." *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1742, 82USPQ2d 1385, 1396 (2007).

9. Claims 14, 15, and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Berry** (US 5,895,428; cited in Applicants' IDS) in view of **Stubstad et al.** (US 3,867,728 A; cited in Applicants' IDS).

Berry discloses the invention as claimed (see 102(b) rejection above), except for particularly disclosing the external plate surfaces as having a deflectable/deformable surface (or mesh) thereon. However, this is well known in the art. For example, Stubstad et al. disclose (see Figures 1, 2, and 4) an intervertebral spacer device (device 10) comprising: (i) first (top element 11) and second (bottom element 12) plate members, each having an external plate surface, at least one of the external plate surfaces having a deflectable/movable (i.e., capable of being deflected/moved; see column 8, lines 46-49; column 9, lines 14-17), convex (see Figure 4; see column 13, lines 24-26), wire mesh (e.g., Dacron mesh 21 and/or Dacron mesh 20; see column 8, lines 6-10 and lines 43-59; column 9, lines 10-18). The device further comprises a force-restoring element (e.g. core 15) disposed between the first and second plate members (see entire document). Stubstad et al. teach said deflectable/deformable, convex wire mesh disposed on said external plate surfaces in order for the external plate surfaces to adapt/match to any small irregularities in the vertebral surfaces and to enable deeper tissue ingrowth on said external plate

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surfaces (see columns 8 and 9). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of an intervertebral spacer device comprising external plate surfaces having a deflectable/deformable, convex wire mesh thereon, as taught by Stubstad et al., with the intervertebral spacer device of Berry, in order for the external plate surfaces to adapt/match to any small irregularities in the vertebral surfaces and to enable deeper tissue ingrowth on said external plate surfaces.

As noted by the United States Supreme Court, if a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill. *KSR*, 127 S. Ct. at 1740. "When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product is not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show it was obvious under 35 U.S.C. 103." *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1742, 82USPQ2d 1385, 1396 (2007).

10. Claims 29, 32, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Berry** (US 5,895,428; cited in Applicants' IDS) in view of **Harrington** (US 5,893,889 A; cited in Applicants' IDS).

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Berry discloses the invention as claimed (see 102(b) rejection above), except for particularly disclosing the device/prosthesis as comprising holes and a fastener extending through each of said holes capable of securing the spring to the second plate. However, this is already known in the art. For example, Harrington teaches (see Figure 2) a spring (54) having holes (60) aligned with holes (52, 53) in a second plate (49), and having fasteners (64, 66) extending through each of said holes in order to securely fix the spring to the second plate (see column 3, lines 52-57). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of a spring having holes aligned with holes in a second plate, and having fasteners extending through each of said holes, as taught by Harrington, with the invention of Berry, in order to securely fix the spring to the second plate.

As noted by the United States Supreme Court, if a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill. *KSR*, 127 S. Ct. at 1740. "When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product is not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show it was obvious under 35 U.S.C. 103." *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1742, 82USPQ2d 1385, 1396 (2007).

Response to Arguments

11. With regards to **Berry** (US 5,895,428; cited in Applicants' IDS), Applicants' arguments filed June 16, 2008 have been fully considered but they are not persuasive.

a. The Applicants argue "*Firstly, element (41) of Berry is not a curved convex surface. In fact, element (41) in Berry is shown as a straight conical surface*". The Examiner respectfully disagrees. Contrary to Applicants assertion, surface 41 is not disclosed as being straight. Further, the surface (as a whole) is convex and curved (particularly around the center of said surface).

b. The Applicants argue "*Secondly, if element (41) is located on the top side of the spring or socket as asserted by the Examiner, element (43) cannot be said to be located on the underside of the spring or socket as required in independent claims 13, 16, and 21 because both elements (41) and (43) of Berry are shown on the same side of member (35)*". The Examiner respectfully disagrees. If fitting 109 is broadly interpreted as the spring/socket, then Figures 9 and 11 clearly show said spring/socket as having a top side with a curved convex surface (e.g., curved convex surface of fitting 109) that extends from the curvate volume and confronts said inner surface of said first plate (plate 35 of fitting 101).

c. The Applicants argue "*Thirdly, element (45) is referred to as an aperture in the specification of Berry and is not a curved concave surface as the Examiner refers to it*". The Examiner respectfully disagrees. If either fitting 109 and/or fitting 105 is broadly interpreted as the spring/socket, then Figures 9 and 11 clearly show said spring/socket as having and an underside with a curved concave surface (**first interpretation:** curved concave surface of fitting 109; **second interpretation:** curved concave bottom surface of fitting 105) that extends from the curvate volume and is spaced from and confronts said inner surface of said second plate (**first**

interpretation: fitting 105, if fitting 109 is interpreted as the spring/socket; **second**

interpretation: fitting 103, if fitting 109 and/or fitting 105 is interpreted as the spring/socket).

d. The Applicants argue “*Fourthly, there is no teaching anywhere in the specification of Berry of a spring. The Examiner asserts fitting (109) is a spring in Berry. Element (109) is referred to as a threaded fitting in Berry that may be used to counteract a load placed on an implant. There is no teaching anywhere in Berry that fitting (109) deflects or acts in any manner like a spring. Therefore, Berry does not disclose or even suggest a spring as claimed in independent claims 13 and 21*”. The Examiner respectfully disagrees.

The curved structure of, e.g., fitting 109 is capable of deflecting or acting as a spring. As Applicants admitted: *Element (109) is referred to as a threaded fitting in Berry that may be used to counteract a load placed on an implant.*

With regards to statements of intended use and other functional statements (e.g., adapted to; etc.), they do not impose any structural limitations on the claims distinguishable over the device of **Berry**, which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959). “[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

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e. The Applicants argue “*Further still, Berry does not disclose or suggest that the inner surfaces of the first and second plates face one another as recited in amended independent claim 13*”. The Examiner respectfully disagrees. The figures clearly show the inner surfaces of the first and second plates as facing one another (e.g., they are not facing away from each other).

f. Regarding newly added claim limitation added to claim 16 (i.e., “a ball having a curved surface facing away from said first plate”), the surface opposite to surface 15 is a curved surface that faces away from the first plate (see Figures 2 and 11).

12. With regards to **Xavier et al.** ‘121, Applicants’ arguments filed June 16, 2008 have been fully considered but they are not persuasive. Applicants’ arguments have been adequately addressed in the 102(b) rejection (above).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (9:00 a.m.-7:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on **(571)272-4749**. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Javier G. Blanco/

Examiner, Art Unit 3774

/Dave Willse/

Primary Examiner, Art Unit 3738